

Aim of the study: The Tension-free Vaginal Tape (TVT), has been used extensively over the last 5 years, as a minimal invasive technique for surgical treatment of stress urinary incontinence(1). The Burch colposuspension (BC) is an invasive technique that has been used over the last two decades with good results as well. Objective of the study was to compare the efficacy of TVT and Burch colposuspension in the treatment of genuine stress incontinence, the complications and the urodynamic findings.

Methods. In this prospective study, participated 35 patients who underwent Burch colposuspension and 36 patients that underwent TVT procedure for the treatment of genuine stress incontinence. Both groups of patients were comparable in relation to their age, number of deliveries and Body mass index(BMI). Mean age for TVT was 46.5 years (range 32-62) and mean age for BC was 48.4 years (range 35-64). Mean parity for TVT was 1.9 +0.8 and for BC was 2.1 +1.1, while mean BMI for TVT was 26.6 + 2.1 and mean BMI for BC was 27.2+2.2. All patients had a full history taken and a complete gynecological examination performed at initial visit and Frequency-Volume charts were completed for 3-4 days. Preoperative urodynamic investigations included filling and voiding cystometry, urethral profilometry and uroflow. Genuine stress incontinence diagnosis was based on the findings of urodynamic investigations and in all patients the severity of GSI was stage II (2). Patients with prolapse more than first degree, previous surgical treatment of stress urinary incontinence, maximal urethral closure pressure less than 30cmH₂O and detrusor instability were excluded from the study.

Results. All the patients were operated under epidural anesthesia. The mean follow-up time was 22 months for TVT and 24 months for Burch colposuspension. The operative time for TVT was significantly shorter compared to BC (mean operative time for TVT 20 minutes, and for BC: 58mins). The severity and duration of postoperative pain for TVT was significantly less compared to BC (Mean duration of pain for TVT: 2.1+1.2 and for BC: 7.4+2.3). Therefore, the need for postoperative analgesia was much less for TVT than for BC. The hospitalisation time for TVT was 2.1+1.1 and was significantly shorter compared to BC(5.7+2.2). The necessary time for return to normal activity was 10 days for TVT and 21 days for BC. The cure rate after 22 months of follow-up for TVT and 24 months for BC were as following: TVT :84% and BC:86%, while the improvement was 7% for TVT and 10% for BC. The incidence of postoperative de novo detrusor instability at 6 months follow-up was 14% for Burch colposuspension and 11% for TVT.

Conclusion: The results of the present study suggest that both TVT and Burch colposuspension are almost equally effective in the management of genuine stress incontinence at two years follow-up. TVT procedure requires much less operative time, has much shorter hospitalization time, with significantly less postoperative pain and faster return to normal daily activities than Burch colposuspension(3). The present study is the first comparing TVT with Burch colposuspension in the management of genuine stress incontinence. It seems that TVT could replace Burch colposuspension in the management of genuine stress incontinence in female patients without significant genital prolapse, but more studies including a larger number of patients with a follow-up period at 5 and 10 years postoperatively are required for safer conclusions to be made.

References:

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7A

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Title (type in CAPITAL LETTERS, leave one blank line before the text):

A RANDOMISED TRIAL OF COLPOSUSPENSION AND TENSION-FREE VAGINAL TAPE (TVT) FOR PRIMARY GENUINE STRESS INCONTINENCE

Introduction

Many surgical procedures have been developed for the treatment of GSI but there is little consensus as to the most effective. Although meta-analyses have suggested that colposuspension is associated with the best surgical results (1, 2), there is only limited data from randomised trials on which to base clinical practice. The TVT (Gynecare, Edinburgh) is a recent development for the treatment of GSI and has potential advantages as a short stay, short convalescence procedure. Cure rates of over 80% have been consistently reported (3).

Aims of study

A multi centred prospective randomised trial comparing TVT with colposuspension as a primary treatment for GSI.

Methods

The trial was conducted in 14 centres in the UK and Ireland and included urologists and gynaecologists, university and district general hospitals. Women with urodynamically proven GSI were randomised to TVT or colposuspension. None had detrusor instability (DI), major voiding problems, prolapse requiring treatment or previous surgery for incontinence or prolapse. TVT was performed under local anaesthesia and sedation.(3). Colposuspension was performed under general or regional anaesthesia.

Assessment performed prior to treatment and at six months post operatively included the following: Bristol female lower urinary tract symptoms questionnaire (BFLUTS), SF-36 health survey, Euroqol, 1 week urinary diary, 1 hour pad test, filling and voiding cystometry and urethral pressure profilometry (in some centres).

Results

344 patients were recruited to the study and randomised. There were 28 withdrawals prior to surgery, 23 in the colposuspension group and 5 in the TVT group. 170 underwent TVT and 146 colposuspension, as per protocol. The two groups were comparable in terms of age, BMI, parity, menopausal status. At six months, 63 (40%) of TVT patients and 48 (38%) of the colposuspension group reported no urinary leakage whatever. However, 103 (66%) and 90 (71%) patients respectively, reported subjective cure of stress incontinence. 115 (68%) of the TVT group and 97 (66%) of the colposuspension group were objectively cured, based on a negative 1 hour pad test, together with no leakage seen on CMG. On CMG alone, the numbers cured were 142 (89%) for TVT and 114 (85%) for colposuspension.

The median blood loss was 50 ml and 135ml for TVT and colposuspension, respectively. Bladder perforation occurred in 15 (9%) the TVT group and in 3 (2%) following colposuspension. Opiate analgesia usage was significantly lower following TVT (21%) than colposuspension (91%). The mean duration of hospital stay was 2.2 days for TVT and 6.5 for colposuspension. 9 patients were rehospitalised in the TVT group and 18 in the colposuspension group.

There was no significant increase in the findings of uterovaginal prolapse and no evidence of an increase in symptoms of dyspareunia or prolapse in either group during the follow up period. 12 (7%) patients in the TVT group and 13 (9%) in the colposuspension group developed DI post operatively, however symptomatic urgency that was bothersome was only reported as a new symptom by 3 patients. Six (7%) patients in each group had evidence of voiding disorder. In one patient the mesh was found exposed in the vagina at follow-up; this was managed simply by trimming of the mesh and closure of the overlying vaginal mucosa.

Discussion

The definition of cure used in this study is stricter than that used in other studies in the literature, hence the cure rates for both procedures appear low. On the basis of leakage demonstrated at cystometry and subjective reporting of stress incontinence, cure rates are comparable with previous series. The cure rate at six months on this definition shows no significant difference between the two procedures. The trial was designed to compare the two procedures rather than to demonstrate equivalence. The number of patients recruited was less than initially expected and

388 Abstracts

equivalence cannot therefore be assumed. Some of the initial concerns about the TVT procedure have centred on bladder perforation rate, vascular injury, tape erosion and de novo detrusor instability. Although 15 perforations are reported here, none of these led to any adverse effects. Overall blood loss was less with TVT than colposuspension, although one patient in the TVT group had a significant vascular injury. Whilst both procedures show an incidence of de novo DI, bothersome urgency as a new symptom appears uncommon.

TVT shows promise as a minimal access, rapid recovery procedure for the treatment of GSI. Cure rates and adverse events appear to be comparable with colposuspension. The follow up within this protocol will continue for a minimum of two years.

KW was supported by a grant from Johnson and Johnson, who also provided materials and additional support to collaborating centres.

1. BJU 1996;78(4):497-510.
2. BJOG 1994;101(5):371-374.
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Title (type in CAPITAL LETTERS, leave one blank line before the text):
URODYNAMIC VARIABLES IN A RANDOMISED COMPARISON OF COLPOSUSPENSION AND TENSION-FREE VAGINAL TAPE (TVT) FOR PRIMARY GSI.

As a primary procedure for GSI, colposuspension is generally considered to be the most effective, giving a cure of up to 85%. (1) An alternative to colposuspension is the TVT (Gynecare, Edinburgh) with reported cure rates of over 80%. (2) A proportion of women develop new symptoms following surgery for stress incontinence. These include symptoms of urgency and urge incontinence. The incidence of detrusor instability (DI) following colposuspension has been reported to be up to 16%, (3) although the incidence of urgency symptoms is not well reported. A significant proportion of women experience delayed voiding following colposuspension, others will have difficulty voiding long-term. (4) Studies of urethral profile pressures before and after incontinence surgery show no consistent changes in resting profiles, but enhancement of pressure transmission following successful procedures. (5)

Aims of study

To evaluate changes in urodynamic variables within the context of a randomised trial comparing TVT to colposuspension as a primary procedure for genuine stress incontinence.

Methods

The trial was conducted at 14 centres in the UK and Ireland and included urologists and gynaecologists, university and district general hospitals. Women with urodynamically proven GSI were randomised to TVT or colposuspension. None had DI, major voiding problems, prolapse requiring treatment or previous surgery for incontinence or prolapse. TVT was performed under local anaesthesia and sedation as described by Ulmsten. (2) Colposuspension was performed under general or regional anaesthesia.

Assessment performed prior to treatment and at six months post operatively included symptom and quality of life questionnaires in addition to 1 hour pad test, filling and voiding cystometry and resting and stress urethral pressure profilometry by microtransducer (in some centres).

Results

344 patients were recruited to the study and randomised. There were 28 withdrawals prior to surgery, 23 in the colposuspension group and 5 in the TVT group. 170 underwent TVT and 146 colposuspension, as per protocol. The two groups were comparable in terms of age, BMI, parity, menopausal status. There was no significant change in

volume at first sensation of filling, cystometric capacity, detrusor pressure rise on filling or provocation for either procedure. Twelve patients (7%) in the TVT group and 13 (9%) in the colposuspension group were recorded as having DI at 6 months post-operatively which was not present pre-operatively.

Overall there was a small reduction in both free flow and catheterised flow, and a small increase in voiding pressure; this was not significantly different between procedures. Voiding difficulty was defined as 2 out of 3 of the following: peak flow <15ml/s; maximum voiding pressure >50cmH₂O; residual volume >100ml. On this basis 6 patients (7%) in each group had voiding difficulty at 6 months post-operatively (complete data on all these variables was available for only 91 patients in each group). Genuine stress incontinence was recorded during cystometry in 17 (10%) patients following TVT and 20 (15%) following colposuspension.

Urethral pressure measurements were available on 48 patients (25 TVT and 23 colposuspension). There no significant changes in resting maximum urethral closure pressure (MUCP) or functional urethral length (FUL) for either procedure. MUCP (stress) and FUL (stress) increased for both procedures; this reflects an increase in pressure transmission ratio (PTR) seen maximally in the second and third quartiles of the functional urethral length following both operations.

	TVT		Colposuspension	
	Pre-op	Post-op	Pre-op	Post-op
MUCP (rest)	45.4	39.2	45.8	48.4
FUL (rest)	30.6	29.7	30.3	32.7
MUCP (stress)	14.2	50.2	9.3	65.6
FUL (stress)	9.4	21.7	6.4	24.3
PTR Q1	86.6	98.0	89.9	106.6
PTR Q2	82.1	109.5	78.2	124.8
PTR Q3	57.0	87.4	63.9	88.6
PTR Q4	19.5	33.2	27.5	36.7

Conclusions

There is a small incidence of both detrusor instability and voiding difficulty at 6 months following both procedures; this is somewhat lower than previously reported in respect of colposuspension. Although patients experience less delay in voiding in the post-operative period following TVT, this is not reflected in subsequent urodynamic variables. The mechanism of cure following these procedures appears to be similar; neither is consistently associated with outflow obstruction. Although the surgical approach in the one case is to the bladder neck, and in the other to the mid-urethra, the enhancement in PTR is in both cases seen across the 2nd and 3rd quartiles of the functional urethral length.

KW was supported by a grant from Johnson and Johnson, who also provided materials and additional support to collaborating centres.

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2. IUGJ & PFD 1996;7(2):81-85.
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5. BJOG 1983;90(10):934-939

8

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TITLE: LAPAROSCOPIC VERSUS OPEN COLPOSUSPENSION: A PROSPECTIVE MULTICENTRE RANDOMISED SINGLE-BLIND COMPARISON

Aims: Burch Colposuspension is an effective operation for the treatment of stress incontinence with long-term objective cure rates exceeding 80% (1). Laparoscopic Burch Colposuspension was described in 1990 and has gained wide popularity in recent years (2,3). With the exception of two small series the introduction of this procedure has proceeded without appropriate randomised controlled trials (4,5). The aims of this study were to evaluate the short-